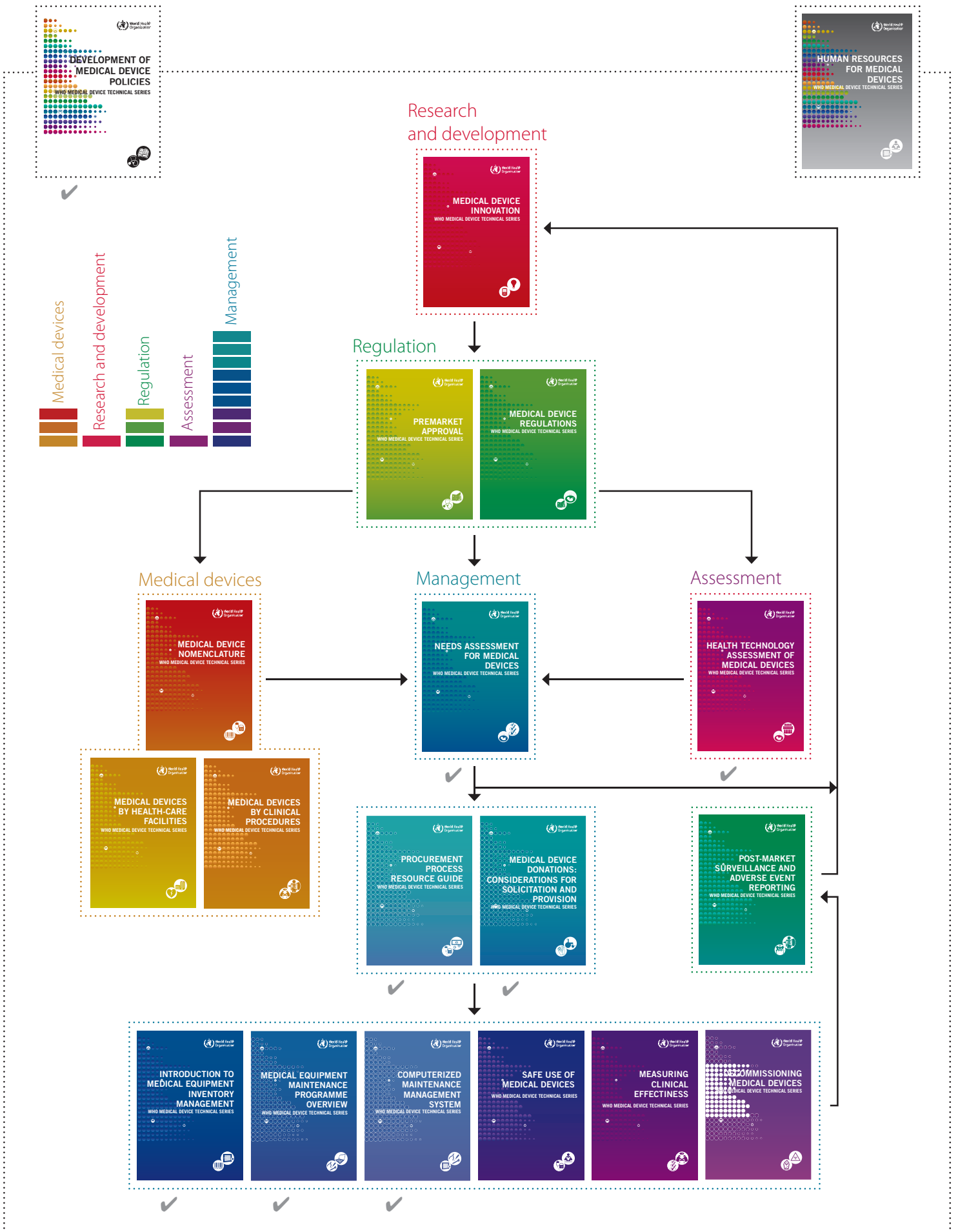




Procurement process resource guide

WHO Medical device technical series





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Preface

Health technologies are essential for a functioning health system. Medical devices in particular are crucial in the prevention, diagnosis, and treatment of illness and disease, as well as patient rehabilitation. Recognizing this important role of health technologies, the World Health Assembly adopted resolution WHA60.29 in May 2007. The resolution covers issues arising from the inappropriate deployment and use of health technologies, and the need to establish priorities in the selection and management of health technologies, specifically medical devices. By adopting this resolution, delegations from Member States acknowledged the importance of health technologies for achieving health-related development goals; urged expansion of expertise in the field of health technologies, in particular medical devices; and requested that the World Health Organization (WHO) take specific actions to support Member States.

One of WHO's strategic objectives is to "ensure improved access, quality and use of medical products and technologies." This objective, together with the World Health Assembly resolution, formed the basis for establishing the Global Initiative on Health Technologies (GIHT), with funding from the Bill & Melinda Gates Foundation. GIHT aims to make core health technologies available at an affordable price, particularly to communities in resource-limited settings, to effectively control important health problems. It has two specific objectives:

- to challenge the international community to establish a framework for the development of national essential health technology programmes that will have a positive impact on the burden of disease and ensure effective use of resources;
- to challenge the business and scientific communities to identify and adapt innovative technologies that can have a significant impact on public health.

To meet these objectives, WHO and partners have been working towards devising an agenda, an action plan, tools and guidelines to increase access to appropriate medical devices. This document is part of a series of reference documents being developed for use at the country level. The series includes the following subject areas:

- policy framework for health technology
- medical device regulations
- health technology assessment
- health technology management
 - › needs assessment of medical devices
 - › medical device procurement
 - › medical equipment donations
 - › medical equipment inventory management
 - › medical equipment maintenance
 - › computerized maintenance management systems
- medical device data
 - › medical device nomenclature
 - › medical devices by health-care setting
 - › medical devices by clinical procedures
- medical device innovation, research and development.

These documents are intended for use by biomedical engineers, health managers, donors, nongovernmental organizations and academic institutions involved in health technology at the district, national, regional or global levels.

Methodology

The documents in this series were written by international experts in their respective fields, and reviewed by members of the Technical Advisory Group on Health Technology (TAGHT). The TAGHT was established in 2009 to provide a forum for both experienced professionals and country representatives to develop and implement the appropriate tools and documents to meet the objectives of the GIHT. The group has met on three occasions. The first meeting was held in Geneva in April 2009 to prioritize which tools and topics most required updating or developing. A second meeting was held in Rio de Janeiro in November 2009 to share progress on the health technology management tools under development since April 2009, to review the current challenges and strategies facing the pilot countries, and to hold an interactive session for the group to present proposals for new tools, based on information gathered from the earlier presentations and discussions. The last meeting was held in Cairo in June 2010 to finalize the documents and help countries to develop action plans for their implementation. In addition to these meetings, experts and advisers have collaborated through an online community to provide feedback on the development of the documents. The concepts were further discussed during the First WHO Global Forum on Medical Devices in September 2010. Stakeholders from 106 countries made recommendations on how to implement the information covered in this series of documents at the country level.¹

All meeting participants and persons involved in the development of these documents were asked to complete a declaration of interest form, and no conflicts were identified.

¹ *First WHO Global Forum on Medical Devices: context, outcomes, and future actions* is available at: http://www.who.int/medical_devices/gfmd_report_final.pdf (accessed March 2011)

Definitions

Recognizing that there are multiple interpretations for the terms listed below, they are defined as follows for the purposes of this technical series.

Health technology: The application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of life.² It is used interchangeably with health-care technology.

Medical device: An article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. Typically, the purpose of a medical device is not achieved by pharmacological, immunological or metabolic means.³

Medical equipment: Medical devices requiring calibration, maintenance, repair, user training, and decommissioning – activities usually managed by clinical engineers. Medical equipment is used for the specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury; it can be used either alone or in combination with any accessory, consumable, or other piece of medical equipment. Medical equipment excludes implantable, disposable or single-use medical devices.

² World Health Assembly resolution WHA60.29, May 2007 (http://www.who.int/medical_devices/resolution_who60_29-en1.pdf, accessed March 2011).

³ Information document concerning the definition of the term "medical device". Global Harmonization Task Force, 2005 (<http://www.ghif.org/documents/sg1/sg1n29r162005.pdf>, accessed March 2011).

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Declarations of interests

Conflict of interest statements were collected from all contributors to and reviewers of the document. Andrew Gammie declared his employment at Fishtail Consulting Ltd., a firm that provides advice in the area of medical devices, particularly in developing countries and Ron Bauer his employment at Saniplan GmbH, a firm that provides technical assistance and consulting services with the aim to improve the quality and accessibility of health systems and services, as remuneration from an organization with an interest related to the subject. None of these declared conflicts influenced the content of the document.

Acronyms and abbreviations

TAGHT	Technical Advisory Group on Health Technology
COCIR	European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry
GIHT	Global Initiative on Health Technologies
HTA	health technology assessment
HTAi	Health Technology Assessment international
IEC	International Electrotechnical Commission
INAHTA	International Network of Agencies of Health Technology Assessment
ISO	International Organization for Standardization
OECD	Organization for Economic Co-operation and Development
PAHO	Pan American Health Organization
UN	United Nations
WHO	World Health Organization



Executive summary

Effective health technology procurement practice leads to safe, equitable and quality health care, and all parties involved enjoy benefits:

- procurement staff gain by carrying out clear and accountable work done to internationally accepted standards;
- funding agencies can have confidence in the right goods being procured at the right price;
- health service professionals gain quality materials and tools;
- most importantly, patients can receive appropriate and effective health-care treatment.

Poor practices in the arena of procurement have given rise to substandard provision or performance of health technology. This document summarizes currently available resources for achieving good practice in this area. It will thus serve as a checklist and planning aid for procurement system development, but will also point the user to more detailed information on each part of the procurement cycle.

Section 6 of this document describes the following standard procurement procedures:

- technology assessment
- device evaluation
- planning and needs assessment
- procurement
- installation
- commissioning
- monitoring.

Section 7 discusses resources that will assist with the following issues:

- local regulations
- replacement of equipment
- refurbished equipment
- radiological equipment
- health information technology
- facilities and construction
- emergencies
- sustainability
- e-procurement
- grievances
- ethical considerations.

Section 8 describes systems for assessing procurement performance, which are used to improve established structures, and boost efficiency and transparency.

1 Introduction

Procurement is a vital element of equitable access to health care. It can be defined as “the acquisition of property, plant and/or equipment, goods, works or services through purchase, hire, lease, rental or exchange” and is taken to include “all actions from planning and forecasting, identification of needs, sourcing and solicitation of offers, evaluation of offers, review and award of contracts, contracting and all phases of contract administration until delivery of the goods, the end of a contract, or the useful life of an asset.” (28, p.6). When procurement includes installation and commissioning, the process can be termed “technology incorporation” (23).

Poor practices in the arena of procurement lead to substandard provision or performance of health technology. This document summarizes currently available resources on how to achieve good practice in procurement. The focus is on medical devices; however, the

principles and processes outlined can also be applied to the procurement of infrastructure facilities and other supplies.

Effective health technology procurement practice leads to safe and quality health care. Other potential benefits of good procurement have been noted in the *How to manage* guide (11, Section 1.2). They include:

- the most economically advantageous terms for the equipment acquired – not necessarily the lowest price obtained through tender, but the best deal for the organization’s needs
- timely delivery and handover
- satisfactory and well-defined terms for delivery, installation, commissioning, training, payment and warranty
- satisfactory after-sales service
- greater interest from the suppliers and manufacturers in submitting offers in the future.

2 Purpose

This document acknowledges and summarizes published health technology procurement guidelines, and provides references to those publications. Users of this document will typically be in a procurement division or hospital management of a national or regional government health service body, concerned with providing a transparent and well-governed procurement service to health practitioners and institutions. Thus, users will generally have a legal obligation to follow accepted best practices in public procurement. The

document is designed to be a practical and comprehensive resource. It will probably be most useful when a new system is being developed, or a fundamental review of services is taking place, in which case United Nations (UN) guidance is available (7). The aim is also to provide a set of indicators for procurement performance assessment. This document is a planning aid and checklist for facilitating system development and operation, but it is not a substitute for a procurement department.

3 Approach

A review of all readily available internationally relevant procurement guidelines was carried out. The guidelines identified are listed in the section, below. The key features of these documents were then collated, categorized and compiled in two formats:

- Section 6 describes the processes and assurances for good procurement;
- Appendix A provides a summary chart (i.e. a checklist) of the processes and assurances, arranged as a quick reference for system development and operation.

In addition, Section 5 contains an overall flowchart, to facilitate system development and advocacy (Figure 2).

These simplified approaches mean that this document is not a stand-alone resource. Rather, it is a tool to help users identify the many resources that may be helpful as they move through the procurement process. The user should follow the references and consult those more detailed materials to achieve a comprehensive approach.

4 Overview of procurement

The Organisation for Economic Co-operation and Development (OECD) notes that four “pillars” are required for a good procurement system (41, p.26):

- legislative framework
- integrity and transparency
- institutional and management capacity
- operations and markets.

Good governance programmes require that public procurement reforms support essential concepts and values, such as:

- *accountability* to establish clear lines of responsibility in decision-making structures;
- *responsiveness* to citizens of the country;
- *professionalism* to improve individual and system performance;
- *transparency* to ensure that procedures and policies are understood by and acceptable to procurers;
- *competition* to attract high-quality national and international partners investing in meeting government needs through contracts;
- *appeal* rights to redress meritorious grievances of suppliers.

An effective public procurement system allows suppliers to provide satisfactory quality, service and price within a timely delivery schedule. The basic tenet of public procurement is contained in what are described by Bailey (9) as the “five rights”: the right product or service of the right quality and right price, and the right quantity, at the right place and time. Although this formula is simple, it involves questions of accountability, integrity and

value, with effects far beyond the actual buyer and seller transactions at its centre.

To obtain the **right product or service**, a generic description within a clear specification is required. The other “rights” are defined below.

Right quality:

- The right description and specifications, with the appropriate quality inspections.
- The description, specifications and inspections set the minimum standard acceptable.
- The description or specifications are generic, and are not suited or aligned to one particular firm or group of firms.
- The description or specifications are unambiguous.
- All tender respondents have equal opportunity in obtaining all relevant details.
- Specifications avoid stating that items will be procured “as per sample”, to ensure transparency.

Right price:

- Rate estimation or justification is based on tangible factors; for example, last purchased rates, published maximum retail price, raw material cost, prices of similar or alternative products, or prevalent industry unit rate price.
- Negotiations or counter offers are rare and, if used, have specific guidelines, criteria and precautions. The tender system aims to obtain the best possible price, and not an unreasonably low price.

- Due diligence is exerted to look at all pages of all the offers received, to ensure that any price implications in the offer are identified.
- Vigilance is maintained, especially in cases of closely competitive tenders and unhealthy, cartel-type situations. Anti-fraud or anti-corruption software is applied when available. Protocols exist for declaring conflicts of interest and tracing accountability for all decisions (see Section 7.11).

Right quantity:

- Right quantity for procurement is justified, taking into consideration all the stocks available. As many requirements for the same item as possible are consolidated, taking into account the shelf-life of items and

the lead time for procurement.

- No major change to the tendered quantity occurs after submission, because this raises suspicion and creates a lack of transparency.
- There is vigilance when it is necessary to distribute quantities among more than one tender respondent (see 9 for additional information).

Right time and place:

- The right time and place for delivery are specifically and exactly stated in the tender (these have a bearing on the price), and the final accepted offer conforms to these factors.
- Logistics of issues such as supply and mode of transport are clearly specified.
- Terms of payment are outlined.

5 Structure

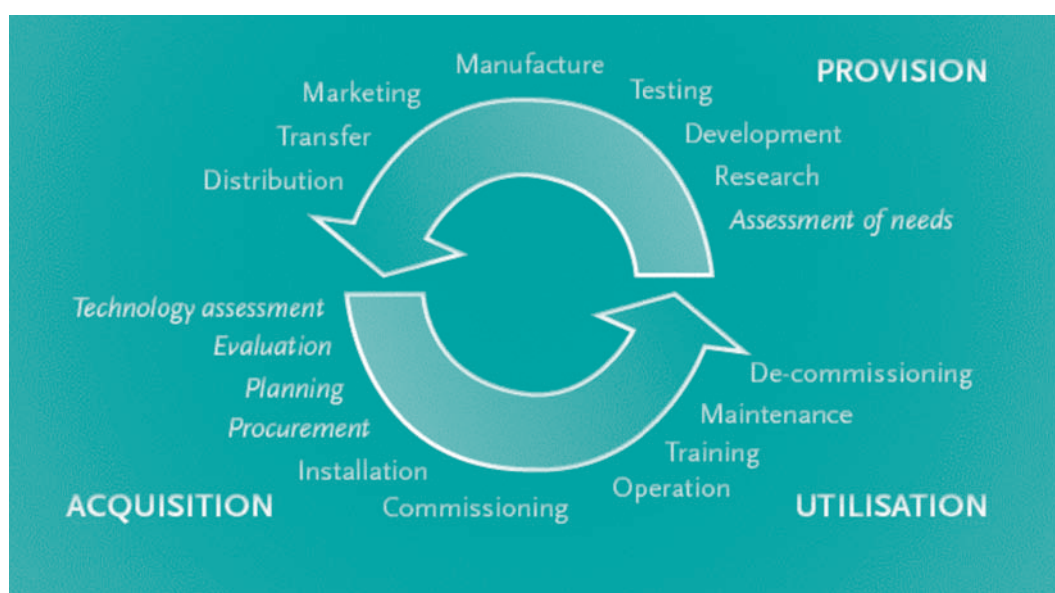
There are many models of procurement workflow and health technology management. The format that is used here is the health technology life-cycle, shown in Figure 1.

The divisions of the acquisition section of Figure 1 are used in Section 6 to provide a stepwise approach to the procurement process. In addition, a “monitoring” section (Section 6.7) summarizes the available resources that describe the processes of informing and controlling procurement management. In Section 6, each element is defined and the pre-existing conditions or inputs are described. A summary is then given of the actions identified by the referenced

source material. A section on assurances provides the user with information to establish mechanisms to monitor the progress of each element. If used in a systematic manner, this stage will help to ensure that procurement occurs as intended. As a measure of success, an output is given for each element, to enable goals to be set for each stage.

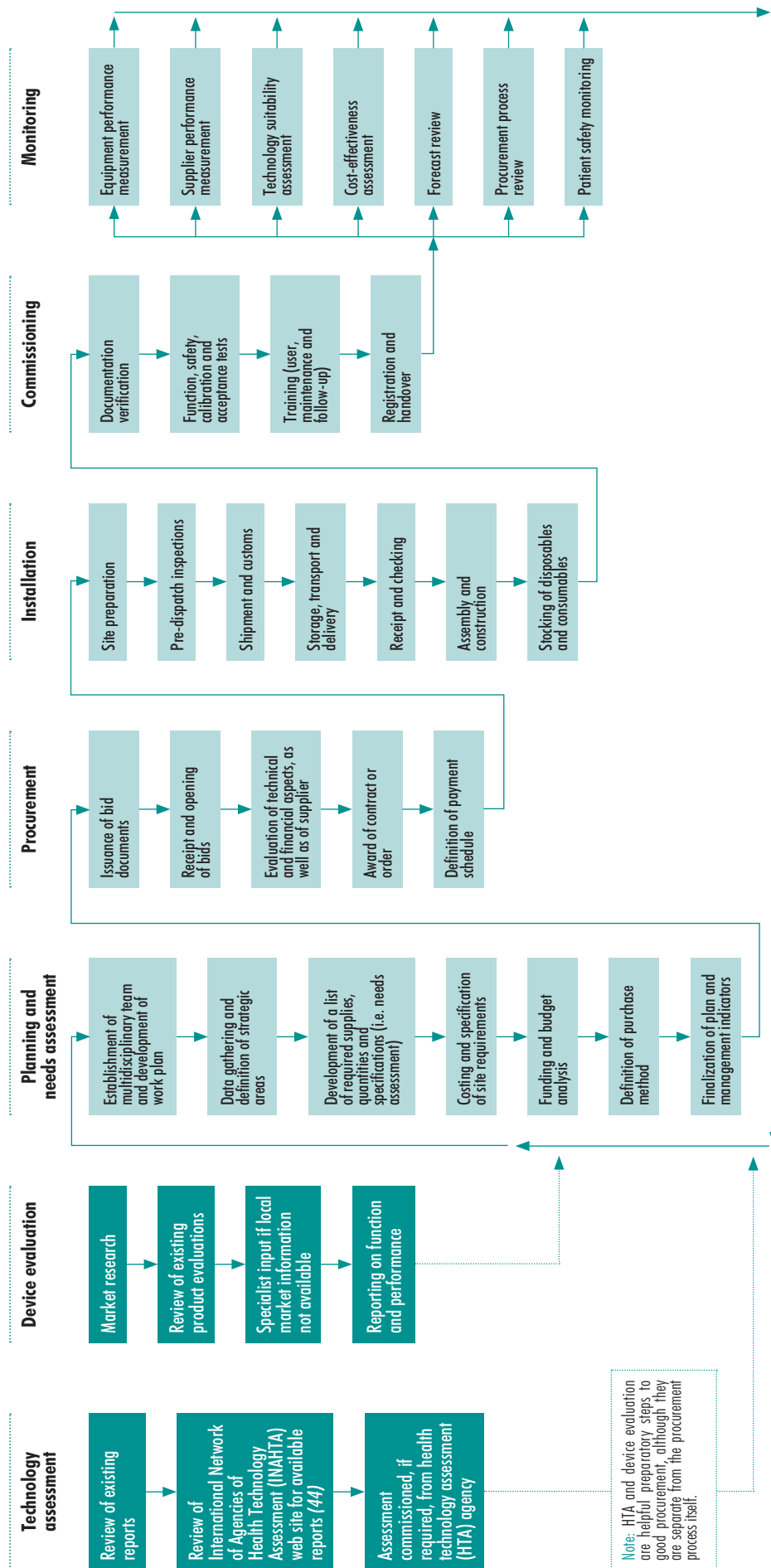
Figure 2 provides a summary flowchart of standard procurement procedures. More detailed flowcharts, specifically for the acquisition cycle, can be found in other national and international guidelines (e.g. 11, Figure 6; 12, p.18; 29, Appendix 10.6; 35).

Figure 1. Health technology life-cycle



Source: (1, p.44)

Figure 2. Summary flow chart of standard procurement procedures



6 The procurement process

6.1 Technology assessment

6.1.1 Definition

Technology assessment is “A multidisciplinary process that summarizes information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner” (56). This definition refers to the technology used in health care, not to a specific device.

6.1.2 Inputs

Access to technology assessment reports is important. The International Network of Agencies of Health Technology Assessment (INAHTA) (44) is the primary resource for reports; it includes the reports prepared by all its member agencies. Health Technology Assessment International (HTAi) is the professional organization that encompasses all interested stakeholders in health technology assessment (HTA). The European Network for Health Technology Assessment evaluates new and emerging technologies (56). Evidence reports (e.g. 43; 45) are also available from other nationally based agencies.

6.1.3 Actions

Existing assessment reports can be used to determine whether an identified health need is effectively met by a given technology. Guidance can then be obtained on the level of procurement required for a given health gain.

Some countries (e.g. 43; 45) undertake device evaluations of their respective markets, but each report starts with a technology overview, and includes references to material that will assist in a more general technology assessment.

Overviews of technologies, treatments and pharmaceuticals are available (e.g. 46; 47), published with the intent to guide health-care practice in their respective countries. Cochrane reviews (57) can also be consulted for information on the evidence base for a given treatment. If guidance is not available, other agencies whose remit includes technology assessment can be contacted for further information. Such agencies include HTAi, INAHTA, EuroScan and WHO collaborating centres (60; 61; 62; 63). Alternatively, a specific assessment can be commissioned.

Additionally, *Health technology assessment of medical devices* (64) in this technical series will serve as a valuable resource.

6.1.4 Assurances

The use of nationally certified or peer-reviewed sources can ensure data integrity. INAHTA can be contacted to check the validity or integrity of such sources, if necessary.

6.1.5 Outputs

Technology assessment helps to ensure that health policies and plans include the real health benefit of a technology (56), which facilitates evidence-based decision-making (44).

6.2 Device evaluation

6.2.1 Definition

Device evaluation is the expert assessment of performance and function of a given device. It is a certified check that a particular device does what the manufacturer claims that it does.

6.2.2 Inputs

To understand the range of products available, it is a good idea to perform market research before evaluating a device. Test laboratories or evaluation centres used for market research or device testing should be registered or certified by a competent authority.

6.2.3 Actions

Various reviews (e.g. 43; 45) can be used to find evaluations of devices in the treatment field, and guidance can be obtained on the performance of devices on the market. However, these reviews are specific to the originating countries, and may not cover all locally available devices. Certification to an International Electrotechnical Commission (IEC) or International Organization for Standardization (ISO) standard (or local equivalent) can be used as an assurance of good performance of a particular design of device, and even as a requirement in tenders. Further advice on function or suitability of particular devices is available (49; 50). If full coverage of the market is not achieved at this stage, it will be necessary to seek advice from a biomedical or clinical engineer, to guide appropriate testing of devices. Information gained through research at this stage can prevent expensive and time-consuming errors later.

6.2.4 Assurances

The use of nationally certified or peer-reviewed sources can help to ensure data integrity.

6.2.5 Outputs

A reliable assessment of the function and performance of available devices will be useful in making purchasing choices (45).

6.3 Planning and needs assessment

6.3.1 Definition

Planning is work that lays out “coordinated and integrated action to fulfill a need for goods, services or works in a timely manner and at a reasonable cost” (26, p.3–2); it is essentially the process of turning health-care delivery requirements into future procurement requirements. A needs assessment involves quantification of gaps between desired health service provision and the current situation.

6.3.2 Inputs

National health policies serve as the starting-point for planning (10, p.5; 12, p.13). There is also a need for an equipment inventory and population data, and for advisory groups to assist in the appropriate application of technology (10; 13). A full example of the contents and layout of a procurement plan can be found in the *UN procurement manual* (27, pp.78–86). The manual includes the need for specifications, timelines, funding sources, market surveys, appropriate approvals and strategies. Guidelines written for Namibia (10, p.5) recommend the inclusion of standard equipment lists for given health facilities. A Pan American Health Organization (PAHO) guide (32, Annex 1) includes a list of requirements for establishing a supply system. The guide also suggests identification of all those who need to take action; reference prices; needs-estimation guidelines; and supplier database and management guidelines. All of these components form part of a standard procurement policy.

6.3.3 Actions

The PAHO guide (32, Section 3) details a stepwise approach to developing a

procurement plan, summarized below (see also 29, Section 3):

- establishment of the procurement planning team;
- drafting of a work plan (web resources, e.g. 3, may be of use);
- data collection and processing, using current inventory (10, p.5) and market research (28, p.32);
- description of critical areas and full needs assessment; further information can be obtained from *Needs assessment for medical devices (65)* in this technical series;
- drafting of a list of strategic equipment and supplies, derived from health needs (e.g. 51; 28, pp.28–31 on how to specify requirements);
- development of specifications (11, Annex 7) and specification outlines (30);
- specification of site requirements and preparations needed;
- analysis of reference prices and delivery times;
- analysis of funding sources;
- adjustment of budget;
- definition of requirements for lifetime support (operation and service manuals, maintenance, spare parts, etc.) in the contract;
- definition of purchase method (11, Section 4; 24, Sections II & III; 26, p.27), including open or restricted tender, direct ordering, competitive negotiation, national or international competitive bid, request for quotes, leasing and long-term agreements;
- definition of management indicators (see Section 8, below);
- finalization of the procurement plan.

Detailed assistance on determining required quantities can be found in the *How to manage* series (11, Section 5), which also includes advice on creating an annual plan; undertaking quantification and prioritization; planning for contingencies; deciding on whether to

use lots, and which procurement model to use; timetabling of procurement; and preparation of paperwork. Other general guidelines on quantification can be found in the WHO guides (33; 34, Section A), which focus mainly on planning for pharmaceuticals, but also include general principles. These principles are laid out in a stepwise fashion in another WHO guide (16). For delivery options, the standard international commercial terms, known as “incoterms” (listed in 11, Annex 8) can be consulted. The option of leasing equipment can be attractive when compared to the high capital cost of some items, and it gives the vendor an incentive to keep equipment operational. Various guides provide help on comparing leasing and purchase (26, p.62; 11, Section 3.3.4). Although ready-to-use (i.e. turnkey) solutions can be attractive, they still require careful contract planning, progress monitoring and acceptance checks.

The *How to manage* guide (11, p.61) lists some advantages of developing a standardization policy, where procurement is limited to a few varieties of a particular type of device. Although this can simplify operations and save money, the policy needs to be regularly reassessed, because technology developments can change which models are most appropriate. There is also the danger of unfair exclusion of suppliers, so the policy will need to be transparently applied and reviewed.

It may be helpful when initially developing a procurement planning system to see examples of:

- vendor selection and inclusion number regulations (27, Section 9.3);
- solicitation document types and formats (24, Section B; 27, Section 9.9);
- tendering process rules (29, Section 4, chart page D-2);

- procurement strategy choices and rules (29, Section 3.4);
- system development tasks (4);
- checklists for equipment planning (18).

If senior authorities need to be convinced of the benefits of investing in careful planning, the *UN procurement practitioner's handbook* (26, p.31) contains a useful list of advantages, with a summary of steps that can be taken.

Extra guidance on putting together a full financial costing can be found in various web resources (e.g. 14; 15, which includes a sample worksheet). A point repeated throughout the resources is that the initial purchase cost of a device is a fraction of the total cost when operation, training and maintenance (including parts, time and tools) are taken into account. Other web resources that will guide processing of data for planning are available (51; 52; 53; 54).

6.3.4 Assurances

Progress of a procurement plan can be monitored using a Gantt chart (see 11, Section 7.1.1, although this example chart would need to be modified to apply to the whole procurement process). The plan should include realistic and regular milestones, so that progress can be tracked during the course of implementation.

6.3.5 Outputs

A plan for the whole acquisition cycle – including product type, quantity, value, due date and location – will be the output for this stage. Details of the expected timing of each stage can be laid out in chart format (as in the PAHO guide 32, p.41); the chart should include indicators for monitoring (see Section 8).

6.4 Procurement

6.4.1 Definition

Procurement is the process of obtaining what is required by the plans.

6.4.2 Inputs

Inputs include procurement policies, procurement plan, specifications, financial approval and a decision on the method of procurement (32, Section 3; 11, Section 4.2).

6.4.3 Actions

The main elements of good procurement practices are listed in the How to manage guide (11, Section 6); they include:

- asking for bids and issuing documents (e.g. 28, Section 5; 31, Section 4);
- receiving and opening bids (e.g. 27, Section 10);
- evaluating bids and comparing them to specifications (e.g. 27, Section 11; 28, Section 6):
 - › checking compliance with bidding rules;
 - › technical evaluation: weighting elements for decision-making (e.g. 17);
 - › financial evaluation;
 - › supplier evaluation (e.g. 12, Section 3.3; 10, p.7);
- awarding contract or placing order (e.g. 28, Section 8; 26, Section 3.9, for an example of contract elements and terms for the UN);
- debriefing unsuccessful bidders;
- scheduling payments (e.g. 28, Section 10.5).

For quality management in manufacturing and purchasing, particularly with regard to ISO9001, see *Medical device regulations – global overview and guiding principles* (1, Section 3.4.4). For an example of applying quality standards to procurement, see *Quality management in purchasing* (2).

For specific funds or donors, there will be related rules to follow (e.g. 25, for the Global Fund for AIDS, Tuberculosis and Malaria), or the UN documents cited above. WHO also offers guidance on prequalification of laboratory diagnostics (58). It is important that negotiation, if included at any stage, be clarified at the outset to all bidders, and performed in a way that conforms to local regulations.

6.4.4 Assurances

Checklists or planning charts (see examples cited in Section 6.3.3) can be prepared with responsibilities for each stage clearly assigned, and an expected timeline.

6.4.5 Outputs

The output from the procurement stage will be the award of one or more contracts, with agreed costs, timescales and specifications.

6.5 Installation

6.5.1 Definition

Installation is “the process of fixing equipment into place” (11, Section 8.3.1). Other related processes are the delivery, storage and placement of procured goods in the desired location.

6.5.2 Inputs

The inputs are completed contract awards or orders, specified materials and the definition of delivery requirements.

6.5.3 Actions

The *How to manage* guide (11, Sections 7 and 8) contains details for the following steps:

- preparation of the site;
- pre-dispatch and sample inspections;
- shipment and customs;
- transport; the PAHO guide (32, pp.26–27) compares different supply and storage routes;

- storage;
- receipt and checking in the presence of supplier (e.g. 10, p.13), and use of a checklist (12, Section 4.1);
- assembly or construction;
- update, checking and stocking of related disposables.

A detailed example of process requirements can be found in the UN procurement manual (27, Section 14).

Adherence to the procurement plan (see Section 6.3) is important, because there are many documented instances of this being a critical stage for procurement success (e.g. see 11). The procurement plan, material specifications, supplier and purchaser contact details, and specific responsibilities should be communicated to all actors in the process.

6.5.4 Assurances

The establishment of a checking and reporting process is important for each stage. For example, during assembly or construction, a checklist with reference to procurement specifications (e.g. 11, Section 8), can be used and reported to the procuring authority. The UN guides emphasize that each of the above stages should also have a reporting route for noncompliance or failure (27, Section 14.6), and they describe the process as part of “contract control” (26, Section 3.10).

6.5.5 Outputs

The outputs from the installation stage will be the health technology delivered, installed and ready for initial use.

6.6 Commissioning

6.6.1 Definition

Commissioning is “a series of tests and adjustments performed to check whether new equipment is functioning correctly and safely ... before the equipment is

used” (11, Section 8.3.2). Training in the use of technology will normally be included with commissioning.

6.6.2 Inputs

The inputs are health technology that is delivered, installed and ready for initial use.

6.6.3 Actions

The *How to manage* guide (11, Section 8.3) describes the following commissioning tasks:

- check documentation;
- prepare for use;
- undertake safety tests, calibration and function tests;
- record results;
- provide training (e.g. see 12, Section 5 for full requirements):
 - › initial training;
 - › training of maintenance staff;
 - › follow-up training;
- enter registration into health-facility records;
- handover (recommended only after the above steps have been completed).

6.6.4 Assurances

A mechanism to record and report on each step of the above is important, and requires an information system of some sort for the management of assets. Reporting personnel at each stage should be qualified (e.g. technically trained staff for safety tests, and users for training and function tests). The checklist developed for installation (Section 6.5.4) can be extended to include commissioning.

6.6.5 Outputs

The outputs for commissioning are technology ready for routine use, users trained for effective operation, and the procuring authority informed of successful commissioning.

6.7 Monitoring

6.7.1 Definition

Monitoring is the gathering and management of data to control current procurement and inform future procurement. Whereas the assurances outlined in the sections above check that each stage occurs properly, the monitoring process feeds back information from the whole cycle to inform planning.

6.7.2 Inputs

The inputs are the goals against which progress is to be compared, and information systems for data recording and analysis.

6.7.3 Actions

The *How to manage* guide (11, Figure 6) emphasizes that feedback should be gathered from each assurance section of the health technology management cycle. Analysis of this data will enable judgement to be made on:

- *equipment performance* – by checking repair and maintenance work required (e.g. down time);
- *supplier performance* (see 32, Annex 5 for tools for supplier management; 27, Section 15; 28, Section 10.1.3; 4, which gives clear reasons for this monitoring) – by checking for:
 - › the proper occurrence and execution of training, warranty visits and service calls;
 - › satisfactory history of delivery;
 - › lack of difficulties with the acceptance of goods;
- *technology suitability* – by checking:
 - › supply of consumables;
 - › actual use of equipment;
 - › feedback from equipment users for specification development;
 - › commitment of practitioners to use the equipment;
- *cost effectiveness* – by comparing actual running and life cycle costs

with forecast, to check that there are no excessive repairs;

- *forecasting accuracy* – by comparing quantities planned with actual orders and requirements;
- procurement processes (see Section 8, below);
- *patient safety* – by:
 - › establishing a monitoring and registry system to track users of implantable devices through patient data (e.g. in the case of such devices being recalled);
 - › determining the appropriate point for devices or facilities to be taken out of service.

These processes require a system for information management and data acquisition. Further information can be obtained from *Computerized maintenance management system (66)* in this technical series. When instituting

a new procurement structure, the information management and data acquisition system must be specified in the initial plans, rather than added later (11, Section 9). The task of procurement does not end with the supply of goods – monitoring is vital to ensure efficient future procurement; it is also cited by the Anti-Corruption Resource Centre (6) as a key feature to guard against corruption.

6.7.4 Assurances

Information management systems can be used to ensure that goals are met, and that sufficient data is gathered to inform good planning.

6.7.5 Outputs

The outputs of monitoring are a database of reliable and effective health technology, suppliers, processes and facilities; and a history of procurement experiences and issues raised.

7 Special considerations

7.1 Local regulations

It is important for procurement departments to conduct thorough research into the local regulations that may be in place. For government agencies, a supplies ministry or equivalent may have legal oversight of all government procurement. Corporate or multilateral groups will have systems to which health-care procurement will need to conform. Each donor group will also have its own requirements for procurement method, payment and reporting. It is the procurer's role to investigate and conform to all of these regulations. Where reference is made to the UN Conference on Trade and Development or to the World Trade Organization, their websites (55) can be checked for details.

7.2 Replacement of equipment

Part of the planning process is to estimate future procurement needs for health technologies. Future needs can be calculated by taking the required quantity and subtracting the current inventory quantity. The values for the current inventory will change over time, as equipment or facilities are removed from service or clinical guidelines change. Thus, an asset management system needs to include an estimate of the useful life of each asset. Replacement of equipment can then be a planned exercise rather than an emergency response. Planned replacement of equipment helps to safeguard patient safety, ensure quality of results and reduce the cost of

repairing old equipment that is no longer supported. In the case of high-volume items, it is best to maintain a stock of replacement items (i.e. to procure slightly more than required at a single point in time). In the case of low-volume, high-cost items, it is more efficient to plan replacement before failure. This will allow for continuous clinical service; also, the replaced items may have some resale value. Examples of replacement criteria can be found in at least one national guide (12, Section 10.1).

7.3 Refurbished equipment

Refurbished equipment is equipment that has already been in use, but has been taken out of service for renewal work by the manufacturer or a third party. Specific guidance can be obtained from the European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR) (19; 20). Information on donated equipment can be found in *Medical device donations: considerations for solicitation and provision* (67) in this technical series and in (21). For both donated and refurbished equipment, great care should be taken in specifying the age, condition, backup technical service and consumable supply that is acceptable to and available for the end user (11, Section 3.4). All of the procurement stages described above should be followed in obtaining such equipment. There may well be national or donor regulations in place governing this type of procurement.

7.4 Radiological equipment

Background information on X-ray equipment and an example of a tender form is provided in a WHO guide (22). Purchase contracts for high-capital radiological equipment will normally include costs of a comprehensive maintenance contract for 10 years. It is important to have certified local service capacity, clear channels for the import of parts, guarantees that incorporate down-time compensation, and clarity of the areas for which the manufacturer and the distributor are responsible. Attention should be given to local and international import, transport and storage regulations; relevant guidance can be obtained from the International Atomic Energy Agency (59).

7.5 Health information technology

Software products are routinely used in health care, with implications for patient safety. Therefore, proper procurement and management practices should be followed, especially since software may be obtained in the form of unregistered copies. Correct procurement of software is important for legal reasons, and because security updates and virus protection will rely on proper manufacturer support. Care should be taken to inspect the end-user licence agreement before a contract is placed, to ensure that the specifications (e.g. number of users, limitations of liability and hardware requirements) are met. As with other health technologies, staff training and comprehensive service agreements are essential for effective installation and use of software.

7.6 Facilities and construction

By their nature, construction projects tend to involve longer and more expensive procurement than other types of procurement. Specialist legal advice can thus be valuable for development of contracts. A careful schedule of payments conditional on external specialist assessments of progress is important. Some countries have adopted a system of compensation payments to unsuccessful second-round bidders, to promote quality of competition at that stage. The project tender should include pre-installation requirements of equipment, especially radiology items and those requiring high voltage or current.

7.7 Emergencies

Emergency relief situations do not allow for the normal time-consuming rules of procurement to be followed, unless sufficient emergency stocks are held. UN departments are allowed to use a fast-track system in certain well-defined situations (28, Section 11). However, the assessment and evaluation stages described above are helpful groundwork for emergency situation readiness. The Anti-Corruption Resource Centre (6) has noted that steps to guard against corruption are particularly necessary in emergency circumstances.

7.8 Sustainability

Sustainability has generally been defined as a programme's ability to deliver or sustain benefits after the donor's technical, managerial and financial support has significantly decreased or ended. During the procurement process,

it will be beneficial to consider whether any supply routes or products will be less manageable or locally acceptable in the longer term. Environmental issues (e.g. types of material, special disposal requirements and hazardous consumables) will also need to be taken into account, because they will affect the longevity and acceptability of benefits delivered. Furthermore, they are becoming increasingly important to both governments and donors. Social aspects of procurement (e.g. labour conditions and human rights) are also factors to consider, because suppliers compliant in these areas are less likely to meet with objections from future funders or client groups. The *UN procurement practitioner's handbook* (26, Section 4.5) has a more in-depth discussion of these issues. A sustainability audit in the planning, implementation and monitoring processes can also be of value.

7.9 E-procurement

The use of electronic data interchange and web-based bidding is seen as a tool for both efficiency and transparency. The UN handbook (26, Section 4.2) explains many of the developments and their application to various stages of electronic procurement. The multilateral development banks have their own site devoted to electronic procurement (5). Security of data is a major issue, and specialist advice is important when developing such a system.

7.10 Grievances

There will be government or agency rules to govern grievances, which are best made clear within contract and bid terms. Procurement departments should be clear as to their liabilities before the purchasing process begins. A well-developed monitoring system can track any grievance issues raised, and thus inform the development of future contracts.

7.11 Ethical considerations

A corporate code of conduct or declaration of values will be an asset in promoting good practices and high standards of ethics in procurement. These issues are discussed in UN documents (28, Section 1.8; 26, Section 4.4). Helpful steps to reduce conflicts of interest can also be found in the procurement advice from The Prescription Project (13). In addition, WHO has a summary list of references that may be useful if an awareness programme is desired (36). As mentioned above in Section 4, vigilance is important in closely competitive tenders, and for avoiding cartel-type situations. Antifraud or anticorruption software should be used, where it is available. Development of protocols for declaring conflicts of interest and tracing accountability for all decisions is also valuable.

8 Assessing procurement performance

8.1 Definition

Data on past procurement can inform and improve future procurement, as highlighted in Section 6.7, above. Any procurement process inherently has objectives, and it is necessary to know whether these are met (see 38 for further discussion). Procurement performance assessment is the measurement of achievements against the objectives.

8.2 System for assessing performance

Guidance is available (39, 40) on gauging how close a current procurement structure is to an ideal, which gives an indication of how that structure can be improved. The OECD has summarized lessons learnt from the experience of different countries (41).

Various tools that may be useful in system development and assessment can be obtained from the *Procurement and supply management toolbox* (48). Once a system has been instituted, data can be gathered to track indicators of procurement performance. A thorough

and sustained review of performance is needed to properly manage the public procurement function. The basic tenet here is that “if you cannot measure it, you cannot manage it”.

8.3 Indicators

Indicators for the procurement process suggested by the UN (26, p.29) and the *How to manage* series (11, box 50) are outlined in Table 1.

The *How to manage* guide recommends attention be given to the practical ease of gathering the indicator data and the potential usefulness of the results (11, Section 9). This particular resource also provides guidelines on quality control monitoring.

A useful checklist format for indicators is found in the PAHO guide (32, Annex 7), and is also referred to (as Annex D-6A) in the UN manual (27, Section 15.3). If further examples are required to inform development, a more complex system can be found in *Local performance indicators for procurement* (37).

Table 1. Performance measures and examples of relevant indicators

Performance measures	Indicators
Efficiency of the competitive process	<ul style="list-style-type: none"> • Number and percentage of compliant bids and proposals • Number of suppliers involved in the competition • Suppliers' feedback on process in structured questionnaire
Cost reduction and containment	<ul style="list-style-type: none"> • Level and amount of savings or cost reductions achieved per item and type • Percentage reduction of stockholdings • Percentage reduction in demand • Number of "stock-outs", averaged per medical store • Number and percentage of goods rejected • Percentage of budget spent
Supplier management	<ul style="list-style-type: none"> • Number and percentage of "new" suppliers involved in competition • Number and percentage of late, damaged or inadequate deliveries • Time taken from contract award to full handover • Level of quality achieved, as a percentage of rejections per supplier • Number and percentage of commissioning jobs delayed, by facility and supplier • Value of purchases from each supplier by year
Efficiency of internal systems and processes	<ul style="list-style-type: none"> • Volume of low-value transactions, as percentage of number of orders and order value • Usage of aggregated or long-term agreements, as percentage of total contracts • Reduction in transaction cost, as department cost per order • Internal customer satisfaction, in structured questionnaire • Percentage of purchases completed
Procurement management	<ul style="list-style-type: none"> • Percentage of procurement officers certified • Number and percentage of staff days for training, in person-days
Quality control of equipment and facilities	<ul style="list-style-type: none"> • Percentage of equipment supplied working after each year of age • Percentage of equipment value spent on repair and maintenance

9 Concluding remarks

As shown by the number of resources referred to here, much guidance is available on good procurement practice. This summary of resources is intended to aid and give structure to the development of efficient and transparent procurement of health technology.

When procurement is carried out in this manner, all parties involved enjoy the benefits:

- procurement staff gain by carrying out clear and accountable work, done to internationally accepted standards;
- funding agencies can have confidence in the right goods being procured at the right price;
- health service professionals gain quality materials and tools;
- most importantly, patients can receive appropriate and effective health-care treatment.



Resources

All URLs accessed 2nd December 2010

Most reference documents are available from the WHO Medical Devices e-documentation centre, either on DVD or through the web site (<http://hinfo.humaninfo.ro/gsd/healthtechdocs>).

General procurement system guidelines

- 1 *Medical device regulations – global overview and guiding principles*, Geneva, World Health Organization (WHO), 2003 (http://www.who.int/medical_devices/publications/en/MD_Regulations.pdf).
- 2 *Quality management in purchasing, ISO 9001 – 2000 Quality management system*, Harlow, EBME Ltd (<http://www.ebme.co.uk/arts/iso/purchasing.htm>).
- 3 *How to design a purchasing process*, Bizbodz.com (<http://www.bizbodz.com/Supply-Chain/General-Supply-chain/How-to-design-a-purchasing-process-1.asp>).
- 4 *Purchasing and supply management model*, Stamford, Chartered Institute of Purchasing and Supply 2003 (http://www.cips.org/Documents/Resources/PSM_model_Feb03.pdf).
- 5 Multilateral Development Banks electronic government procurement portal (www.mdb-egp.org).
- 6 *Corruption in health sector procurement*, Bergen, Anti-Corruption Resource Centre (<http://www.u4.no/themes/procurement/procurementinhealth.cfm>).
- 7 *United Nations Procurement Capacity Development Centre*, New York, United Nations (www.unpcdc.org).
- 8 *UN common guidelines for procurement*, New York, United Nations, 2006 (http://www.iapso.org/pdf/gbg_master.pdf).
- 9 Bailey KD (1994). *Typologies and taxonomies: An introduction to classification techniques*, Sage Publications, Thousand Oaks, CA.

Guidelines specific to medical devices

- 10 *Procurement of medical equipment, Chapter 1 of MEM guidelines*, Government of Namibia, 2003 (<http://www.healthnet.org.na/documents/guidelines/MEM%20Guidelines%20Final.zip>).

- 11 Kaur M et al. *How to procure and commission your healthcare technology*. 'How to Manage' series of health care technology guides no. 3. St Albans, Ziken International (Health Partners International), 2005.
- 12 *Managing medical devices DB2006(05)*, Department of Health, United Kingdom, 2006 (<http://www.mhra.gov.uk/Publications/Safetyguidance/DeviceBulletins/CON2025142>).
- 13 *Drug and medical device procurement – A toolkit for academic medical centres*, Boston, The Prescription Project (http://www.prescriptionproject.org/tools/initiatives_resources/files/0014.pdf).
- 14 *Procurement of medical equipment for the 21st century*, Harlow, EBME Ltd. (<http://www.ebme.co.uk/arts/procurement>).
- 15 *How to decide whether to buy new medical equipment*, Leawood, American Academy of Family Physicians, 2004 (<http://www.aafp.org/fpm/2004/0300/p53.html>).
- 16 *Procurement and management of supplies and equipment (from Medical supplies and equipment for primary health care)*, Geneva, WHO, 2001 ([http://www.who.int/management/resources/procurement/MedicalSuppliesforPHC\(2\)Procurement&Management.pdf](http://www.who.int/management/resources/procurement/MedicalSuppliesforPHC(2)Procurement&Management.pdf)).
- 17 *Guide to objective evaluation of equipment tenders, Annex 5 of MEM guidelines*, Government of Namibia, 2003 (<http://www.healthnet.org.na/documents/guidelines/MEM%20Guidelines%20Final.zip>).
- 18 *Hospital technology – procurement subsidy checklist for health care equipment*, Stuttgart, FAKT-Consult, 1999 (<http://www.fakt-consult.de>).
- 19 *COCIR good refurbishment practice – medical equipment*, Brussels, European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR) 2009 (http://www.cocir.org/uploads/documents/-560-cocir_industry_standard1806.pdf).
- 20 *COCIR good refurbishment practice – medical imaging*, Brussels, COCIR, 2009 (http://www.cocir.org/uploads/documents/46-907--39-final_grp_report_2009.pdf).
- 21 *Guidelines for healthcare equipment donations*, Geneva, WHO, 2000 (http://www.who.int/hac/techguidance/pht/1_equipment%20donationbuletin82WHO.pdf).
- 22 *Consumer guide for the purchase of X-ray equipment*, Geneva, WHO, 2000 (http://whqlibdoc.who.int/hq/2000/WHO_DIL_00.1.pdf).
- 23 Wang B (2009), *Strategic Health Technology Incorporation, in Synthesis lectures on biomedical engineering*, JD Enderle (ed.), Morgan & Claypool, Princeton NJ.

Guidelines specific to an organization or country

- 24 *Guidelines procurement under IBRD loans and IDA credits*, Washington DC, International Bank for Reconstruction and Development 2006 (http://siteresources.worldbank.org/INTOFFEVASUS/Resources/WB_Procurement_Guidelines_10_2006.pdf).
- 25 *Guide to the Global Fund's policies on procurement and supply management*, Geneva, WHO, 2004 (<http://www.who.int/hdp/publications/13h.pdf>).
- 26 *UN procurement practitioner's handbook*, New York, United Nations (UN) 2006 (http://www.unicef.org/supply/files/UN_Practitioners_Handbook.pdf).
- 27 *UN procurement manual*, New York, UN, 2010 (<http://www.un.org/Depts/ptd/pdf/pmrev6.pdf>).
- 28 *UNOPS procurement manual*, New York, UN Office for Project Services 2010 (http://www.unops.org/SiteCollectionDocuments/Procurement/docs/UNOPS_procurement_manual_EN.pdf).
- 29 Government of India, *Ministry of Health and Family Welfare procurement manual 2010* (www.mohfw.nic.in).
- 30 New Delhi, *Ministry of Health and Family Welfare compendium of Technical Specifications*, 2010 (www.mohfw.nic.in).

Pharmaceuticals procurement guidelines with relevance to medical devices

- 31 *Practical guidelines on pharmaceutical procurement for countries with small procurement agencies*, Geneva, WHO, 2002 (<http://apps.who.int/medicinedocs/en/d/Jh2999e>).
- 32 *A practical guide for procurement planning and management of strategic public health supplies*, Pan American Health Organization 2006 (<http://new.paho.org/hq/dmdocuments/2008/GuideforProcurementPlanning.pdf>).
- 33 *Operational principles for good pharmaceutical procurement*, Geneva, WHO, 1999 (<http://www.who.int/3by5/en/who-edm-par-99-5.pdf>).
- 34 *Procurement of vaccine for public sector programmes*, Geneva, WHO, 2003 (http://whqlibdoc.who.int/hq/2003/WHO_V&B_03.16_eng.pdf).
- 35 *Procurement strategies for health commodities*, Arlington, United States Agency for International Development (USAID) DELIVER Project, 2006 (http://deliver.jsi.com/dlvr_content/resources/allpubs/policypapers/ProcStraHealComm.pdf).
- 36 *Medicines; corruption and pharmaceuticals*, Geneva, WHO, 2009 (<http://www.who.int/mediacentre/factsheets/fs335/en/index.html>).

Procurement assessment tools

- 37 *Local performance indicators for procurement*, London, Improvement and Development Agency 2005 (<http://www.idea.gov.uk/idk/aio/1709573>).
- 38 *Benchmarking the hospital logistics process*, Richmond Hill, Poulin, Management Magazine 2007 (<http://logisticsmanagementandsupplychainmanagement.wordpress.com/2007/03/27/benchmarking-the-hospital-logistics-process>).
- 39 *Logistics system assessment tool*, Arlington, United States Agency for International Development, 2009 (http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/LSAT.doc).
- 40 *Monitoring and evaluation indicators for assessing logistics systems performance*, Arlington, USAID, 2006 (http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/ME_Indi.pdf).
- 41 *Compendium of country examples*, Paris, Organisation for Economic Cooperation and Development, 2008 (<http://www.oecd.org/dataoecd/18/37/42107830.pdf>).
- 42 *Managing and monitoring suppliers' performance*, Queensland Government, Australia, 2000 (http://www.qgm.qld.gov.au/00_downloads/bpg_monitoring.pdf).

Web resources for equipment and standards information

- 43 ECRI Institute (www.ecri.org).
- 44 International Network of Agencies for Health Technology Assessment (www.htai.org), see also (www.inahta.org).
- 45 Centre for Evidence-Based Purchasing (<http://nhscep.useconnect.co.uk>).
- 46 National Institute for Health and Clinical Excellence (www.nice.org.uk).
- 47 Federal Drug Administration (www.fda.gov).
- 48 Procurement and Supply Management Toolbox (www.psmtoolbox.org).
- 49 MD Buyline (www.mdbuyline.com).
- 50 Medical Equipment Donations Assessment and Advisory Service (www.biomedea.org/http/donations.htm).
- 51 Integrated Healthcare Technology Package (www.ihtp.info).
- 52 Planning and Management of Assets in the Health Services PLAMAHS (www.heartware.nl).
- 53 Activity DataBase (www.adb.dh.gov.uk).

- 54 International Health Facility Assessment Network (www.ihfan.org).
- 55 United Nations Conference on Trade and Development (www.unctad.org), World Trade Organization (www.wto.int).
- 56 European Network for Health Technology Assessment (www.eunethta.net).
- 57 Cochrane Reviews (www.cochrane.org/reviews).
- 58 WHO Prequalification of Diagnostics Programme, Diagnostics and Laboratory Technology, WHO (www.who.int/diagnostics_laboratory/evaluations/en).
- 59 The International Atomic Energy Agency (<http://www.iaea.org>).
- 60 Swedish Council on Health Technology Assessment, Stockholm (<http://www.sbu.se/en>).
- 61 Fudan University, Shanghai (<http://chta.shmu.cn>).
- 62 CENETEC, Mexico (<http://www.cenetec.salud.gob.mx>).
- 63 Institute for Population Health, Ottawa (<http://www.iph.uottawa.ca>).

WHO Medical device technical series

- 64 *Health technology assessment of medical devices*. Geneva, World Health Organization, 2011.
- 65 *Needs assessment for medical devices*. Geneva, World Health Organization, 2011.
- 66 *Computerized maintenance management system*. Geneva, World Health Organization, 2011.
- 67 *Medical device donations: considerations for solicitation and provision*. Geneva, World Health Organization, 2011.

Appendix A

Summary of elements in the medical device procurement process

Element (section number)	Inputs (prerequisites for element)	Assurances (steps to ensure successful completion)	Outputs (deliverables from element)	References used and relevant guidelines or sources for further information
Technology assessment 6.1	Access to technology assessment agency reports	Use of nationally certified or peer-reviewed sources, to ensure data integrity	Helps to ensure that health policies and plans include the real health benefit of a technology, which allows evidence-based decision-making	43; 44; 45; 46; 47; 56; 57; 60; 61; 62; 63
Device evaluation 6.2	Knowledge of current market, and functional, certified device evaluation centres	Use of nationally certified or peer-reviewed sources, to ensure data integrity	Reliable assessment of the function and performance of available devices	43; 45; 49; 50
Planning and needs assessment 6.3	Health policy, inventory, population data and funding sources	Planning chart with milestones	A detailed plan for the whole acquisition cycle that includes indicators for monitoring	3; 4; 10; 11; 12; 14; 15; 16; 18; 24; 26; 27; 28; 29; 30; 32; 33; 34; 51; 52; 53; 54
Procurement 6.4	Procurement policies, procurement plan, specifications, financial approval, decision on procurement method	Checklists or planning chart with responsibilities and timescales	Contract(s) awarded with agreed costs, timescales and specifications	1; 8; 10; 11; 12; 17; 25; 26; 27; 28; 31; 32; 58
Installation 6.5	Completed contract awards or orders, specified materials on hand and delivery requirements defined	Checking and reporting process, with continuous monitoring and control	Health technology delivered, installed and ready for initial use	10; 11; 12; 26; 27; 32
Commissioning 6.6	Health technology delivered, installed and ready for initial use	Reporting and recording by qualified personnel	Technology ready for routine use, users trained for effective operation, and procuring authority informed of successful commissioning	11; 12
Monitoring 6.7	Clear goals and information system for data recording and analysis	Information system to ensure goals are met and sufficient data is gathered	Database of health technology, suppliers, processes and facilities; and history of procurement experiences and issues raised	6; 11; 27; 28; 32; 42



Department of Essential Health Technologies

World Health Organization

20 Avenue Appia

CH-1211 Geneva 27

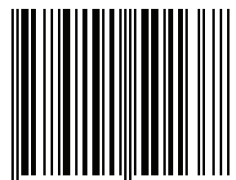
Switzerland

Tel: +41 22 791 21 11

E-mail: medicaldevices@who.int

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